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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/691,051	10/19/2000	Ronald P. Lesser	P 268412 DM-3580	5363
909	7590	11/26/2003	EXAMINER	
PILLSBURY WINTHROP, LLP			OROPEZA, FRANCES P	
P.O. BOX 10500			ART UNIT	PAPER NUMBER
MCLEAN, VA 22102			3762	

DATE MAILED: 11/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/691,051	LESSER ET AL.
	Examiner	Art Unit
	Frances P. Oropeza	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 11/12/03 (Amendment and Declaration).

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 35-60 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 35-46 and 49 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 47,48 and 50-60 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) The translation of the foreign language provisional application has been received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Substitute Specification***

1. The substitute specification filed 11/12/03 has been entered into the record.

***Response to Election/Restrictions Arguments***

2. The Applicant arguments regarding the restriction requirement have been fully considered.

The Applicant asserts the Applicant's have not been given the opportunity to identify the claims that correspond to the asserted species themselves. The first species, claims 36-39, relate to the type of physiological activity sensed; the Applicant elected electrical activity (claim 36) in Paper No. 12, page 2, line 4. The second species, claims 40 and 46-50, relate to the type of medical disorder; the Applicant elected epilepsy (claim 40) in Paper No. 12, page 2, line 4. When the Applicant traversed the restriction, the Examiner included claims 46 and 49 in the claims to be examined based on the inclusion of seizure in the Markush group of claim 46, and based on epilepsy being recognized as a disease of the central nervous system. This restriction requirement is made final.

***Declaration***

3. The joint declaration under 37 CFR 1.132 filed 11/12/03 is sufficient to overcome the rejection of claims 35-46 and 49 based upon the Dorfmeister et al. (US 5995868) applied under 35 U.S.C. 102(e). A new grounds of rejection is established in the subsequent paragraphs.

***Claim Rejections - 35 USC § 103***

4. Claims 35-40, 43, 45, 46 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorfmeister et al. (US 5995868) in view of Mizuno-Matsumoto et al. (IEEE article).

Dorfmeister et al. disclose a system that monitors electrical signals representative of a subject's brain activity and analyzes the signals using a processor (12) to enable treatment (col. 4 @ 64 – col. 5 @ 6; col. 8 @ 37-48). The treatment can be electrical stimulation, cooling or a medicament (col. 6 @ 50-62; col. 9 @ 10-27; col. 32 @ 45-58). Additional sensors provide data on the condition of the patient, including chemical and thermal sensors (col. 9 @ 40-67; col. 13 @ 18-28 and 55-59). Signal processing includes adaptive analysis of waveform characteristics such as wavelet transform analysis (col. 5 @ 6-10; col. 16 @ 32-41).

As discussed in the previous paragraph of this action, Dorfmeister et al. discloses the claimed invention except for the analysis being a cross-correlation analysis.

Mizuno-Matsumoto et al. teach non-stationary analysis of epileptogenic phenomena using wavelet cross-correlation for the purpose of identifying and visualizing the localization of epileptogenic foci. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used cross-correlation analysis in the Dorfmeister et al. system in order to identify the origin of epileptogenic foci and the propagation path so treatment can be precisely applied (page 271, right column, first paragraph and final paragraph; page 272, right column, first complete paragraph; page 273, the paragraph spanning the left and right column; page 275, left column, first complete paragraph; page 277, right column, second complete paragraph).

5. Claim 41 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorfmeister et al. (US 5995868) in view of Mizuno-Matsumoto et al. (IEEE article) and further in view of Ward et al. (US 5978702). As discussed in paragraph 4 of this action, modified Dorfmeister et al. disclose the claimed invention except for the treatment being electrical pulses (claim 41) and the medicament being a drug such as dopamine agonist (claim 44).

As to the pulses, Ward et al. disclose electrical stimulation techniques for treating epilepsy and teach that it is known to use stimulation pulses to increase medicament efficacy (col. 8 @ 44-46; col. 9 @ 10-12). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified system that analyzes signals representative of a subject's brain activity as taught by modified Dorfmeister et al., with the inclusion of stimulation pulses as taught by Ward et al. to provide a proven means to optimize the impact of the medicament so the seizure is arrested as soon as possible.

As to the drug, Ward et al. disclose drug infusion techniques for treating epilepsy and teach that it is known to use a dopamine agonist to alter the neural environment of the brain (col. 8 @ 37-43 and Table I.). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified system that analyzes signals representative of a subject's brain activity as taught by modified Dorfmeister et al., with the inclusion in the medicament delivery system of a dopamine agonist as taught by Ward et al. to provide a specific drug that will alter the neural environment of the brain and alleviate the neural symptoms, specifically seizures.

6. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dorfmeister et al. (US 5995868) in view of Mizuno-Matsumoto et al. (IEEE article) and further in view of King et al. (US 5925070). As discussed in paragraph 4 of this action, modified Dorfmeister et al. discloses the claimed invention except for the charge balance of the current pulse sequence being ordered and maintained by dynamic feedback.

King et al. disclose controlling the locus of excitation of electrically excitable tissue and teach that it is known to provide tissue stimulation based on dynamic feedback to maintain charge balance (col. 10 @ 43-65) to enable optimum tissue stimulation. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified system that analyzes signals representative of a subject's brain activity as taught by modified Dorfmeister et al., with the pulse sequencing using charge balancing as taught by King et al. to provide optimum tissue stimulation by ensuring, with charge balancing, that the tissue is not damaged or destroyed by the imbalance in the charge field during the treatment periods.

***Statutory Basis***

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Other Prior Art Cited***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5314458 to Najafi et al. teaches charge balancing. US 6594524 to Esteller et al. teaches coherence and cross-correlation (col. 14 @ 60-64; col. 27 @ 55-59; col. 30 @ 10-17).

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3762

FPO  
11/24/03

Angela D. Sykes

ANGELA D. SYKES  
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